Received: 7 March 2018 | Revised: 18 May 2018 | Accepted: 26 June 2018
DOI: 10.1002/rcs.1943

ORIGINAL ARTICLE

WILEY The International Journal of Medical Robotics and Computer Assisted Surgery

A novel remote-controlled robotic system for cerebrovascular intervention

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Funding information
High Technology Research and Development Program of China, Grant/Award Number: 2015AA043203; National Natural Science Foundation of China, Grant/Award Numbers: 61672341, 61471349, 61190124 and 61190120; Science and Technology Commission of Shanghai municipality, Grant/Award Number: 17441903800; Basic Discipline Layout Project of Shenzhen City, Grant/Award Number: JCYJ20150731154850923; Shenzhen Engineering Laboratory for Key Technology on Intervention Diagnosis and Treatment Integration

Abstract

Background: In cerebrovascular intervention (CVI), the use of robots has considerable advantages over conventional surgery. This study introduces a remote-controlled robotic system, including the first *in vivo* proof-of-concept trial.

Methods: The robotic system uses a master–slave control strategy. Omega 3 was selected as the master manipulator, and the slave side executed the procedure of inserting the guidewire and balloon catheter, and angiography. The first *in vivo* trial was conducted to test whether the guidewire could be successfully moved from a pig's femoral artery to its carotid artery using our robotic system.

Results: The insertion of the guidewire and balloon catheter and the angiography were successfully accomplished without any vascular rupture. The guidewire was successfully inserted into the secondary branches of the pig's carotid. The robot-assisted surgery took a little more time than manual surgery.

Conclusions: The successful first *in vivo* trial indicates the feasibility and effectiveness of the robotic system.

KEYWORDS

CVI, first *in vivo* trial, master–slave, robotic system

1 | INTRODUCTION

Today, cerebrovascular diseases pose a severe threat to human health.[1,2] Cerebrovascular intervention (CVI) has been appraised as a minimally invasive approach for treating these diseases. However, conventional CVI has a number of shortcomings. First, the medical staff are exposed to high doses of X-ray radiation. Second, the surgeons get fatigued by wearing a heavy lead suit. Third, some human factors, such as trembling of hands and surgical skills/experience, may affect the surgery. The emergence of CVI robots addresses these issues. CVI robotic systems are usually built according to a master–slave architecture with remote control, where the surgeon operates a master device located at a safe distance from the source of ionizing radiation. The surgeons thus avoid the high doses of X-ray radiation and do not need to wear the heavy lead suit. The robotic systems have integrated error-suppression functions, such as motion scaling, which increases safety during the intervention. Owing to such potential advantages, there has been increased interest in CVI robots among researchers and in the industry.

In the last few years, numerous studies have been conducted on the development and use of CVI robotic systems.[3-6] Arai *et al.*[7] developed a 'linear stepping mechanism' to drive a catheter (called the *progressive driving method*). With this mechanism, similar to an automatic

Hao Shen and Cheng Wang contributed equally to this paper
[Correction added on 8 August 2018, after first online publication: The details of the third author, Shoujun Zhou, have been added in the correspondence section in this current version.]

pencil, the catheter is gripped and advanced step by step. Guo *et al.*[8,9] designed a friction-wheel driving mechanism (called the *friction-wheel driving method*). This method used two friction wheels. With the wheels' rotation driven by a motor, the friction would advance the catheter. The two friction wheels are fixed on a rotation gear, so the catheter could be rotated with the rotation gear. Similarly, Srimathveeravalli *et al.*[10] also designed a friction-wheel driving mechanism. The company Hansen[11,12] designed the *Sensei* Catheter Robot System, which also applies the friction wheel method. Combined with medical imaging, surgeons used an operating arm to control the mechanism, which could advance and rotate the catheter. Corindus[13-15] conducted a human PCI (percutaneous coronary intervention) trial of a friction-wheel driving robotic system. Catheter Robotics[16] developed a remote-controlled catheter system called *Amigo*. With this mechanism, a catheter is continuously advanced (called the *continuous driving method*) while being rotated. Fu[17] developed a shape memory alloy (SMA) catheter robot. Three SMA springs are mounted at the tip of the catheter. By controlling the magnitude of the current to heat the springs, different degrees of deformation are achieved, which produces different levels of force to control the tip in order to bend it at different angles for passage through the blood vessel branches. STEREOTAX[18-20] developed the *Niobe*® magnetic navigation system. The system uses magnetic force: two permanent magnets are located on opposite sides of the patient table to provide the driving force. It can control a catheter equipped with magnetic matter at its tip when moving in the blood vessels. An ionic polymer–metal composite (IPMC) material[21-23] was used to drive the catheter. IPMC is a type of electroactive material with characteristics of low electric driving potential, large deformation and aquatic manipulation. These studies used the material as an actuator to drive the catheter.

Each of the above-mentioned methods has significant drawbacks. One step of the *progressive driving method* has such a short travel that surgeons have little operating space. Simultaneous propulsion and rotation of the catheter is only possible over the length of one discrete step. Slippage of the *friction-wheel driving method* can disturb the control accuracy. This method allows continuous propulsion with simultaneous rotation over larger distances than the *progressive driving method*. The mechanism of the *continuous driving method* is too heavy, and the fixed length limits the advancement length. The other methods change the shape and property of the catheter/guidewire, and mass production and promotion are difficult.

To overcome these drawbacks, a remote-controlled robotic system for CVI was developed. The robotic system, combining the advantages of three approaches (the *progressive driving method*, *friction-wheel driving method* and *continuous driving method*) and avoiding their disadvantages, achieves the functions of advancement of the catheter/guidewire and rotation and angiography. Based on real-time fluoroscopic imaging and force feedback, surgeons operate a master manipulator (MMN) to control a slave manipulator (SMN) that advances the catheter/guidewire. The robotic system was used to advance a guidewire from a pig's femoral artery to its carotid artery and to inject a contrast agent.

2 | MATERIALS AND METHODS

2.1 | The CVI robotic system

The customized CVI robotic system (Figure 1) is composed of a main console platform, a slave catheter/guidewire driving mechanism and a robot arm. Figure 1(A) shows the components of the patient side, and Figure 1(B) shows the main console platform. The main console platform is equipped with the MMN, PC controller and display centre. The slave catheter/guidewire driving mechanism aims to drive the catheter/guidewire into the body and accomplish the angiography. The robot arm has 4 passive degrees of freedom (DoFs) and aims to support and position the SMN.

Based on the analysis of the CVI procedures, our CVI robotic system is used for advancement of the guidewire and balloon catheter and injection of the contrast agent, especially advancement of the guidewire. Insertion of the guidewire is the most difficult and important procedure in the CVI. Therefore, the design of the SMN (Figure 2) mainly achieves these functions. The actuator is used to advance the guidewire and balloon catheter into the target vessels and to conduct angiography. It consists of 4 modules: guidewire driving module, balloon catheter driving module, angiographic injector driving module and guidewire/catheter support module.

The guidewire driving module combines the advantages of the *progressive driving method* and *continuous driving method* to advance

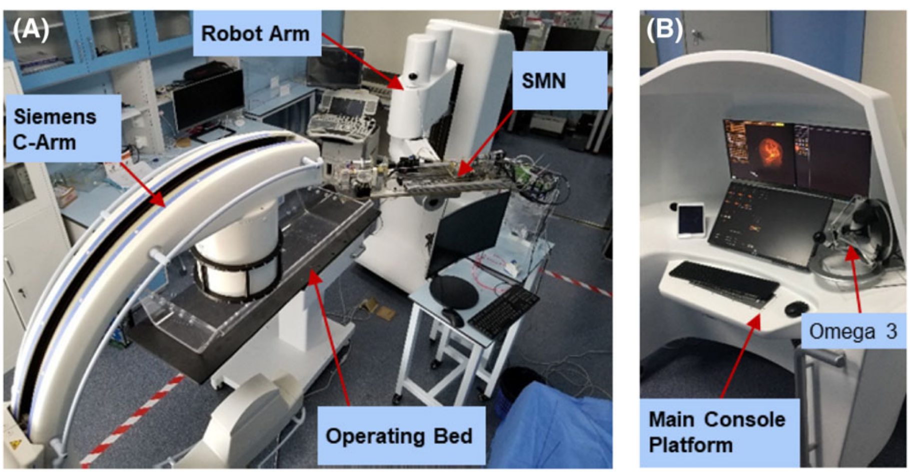

FIGURE 1 Components of the CVI robotic system

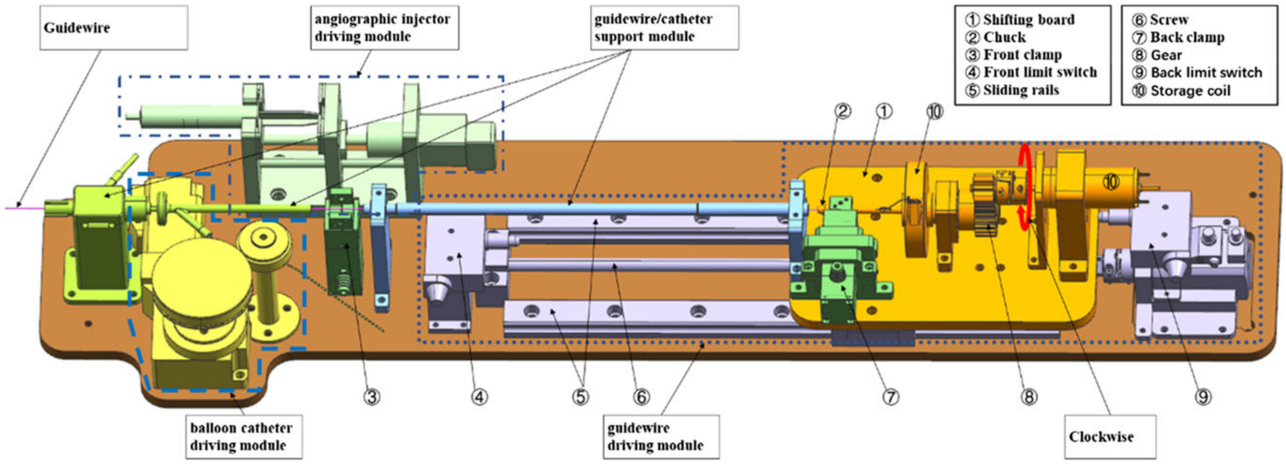

FIGURE 2 Model diagram of the SMN

and rotate the guidewire. The module includes a translation mechanism, rotation mechanism and 6-axis force/torque transducer (ATI Industrial Automation, Nano17, SI-25-0.25). The transducer is in the storage coil, which is used to store the guidewire. The guidewire can move freely inside the storage coil. The translation mechanism uses two sliding rails and a screw to create the pathway for the shifting board. The shifting board fixed on the slide blocks can smoothly follow the screw's movement, which achieves the function of guidewire advancement. The rotation mechanism connected to the transducer can rotate independently, which achieves the function of guidewire rotation. A chuck in front of the transducer, similar to a surgeon's hands, can clamp different sizes of CVI instruments with diameters ranging from 0.3 to 3.5 mm. Maxon (Maxon motor, RE30) and Oriental motors (Shanghai Oriental Motor Co., AZM46AK and AZM24AK) are selected to drive the modules. The module allows simultaneous advancement and rotation of the guidewire. The *progressive driving method* accomplishes long-distance advancement of the guidewire step by step. A single step is 200 ± 0.5 mm. The progressive procedure relies on coordination between two electric clamps, two limit switches and the rotation motor (Figure 3). At the beginning, the shifting board moves forward with the fastened chuck (clamping the guidewire). When the board hits the front limit switch, the two clamps fasten and the back clamp fastens the chuck. The rotation motor then rotates counterclockwise four times to loosen the chuck. Then, the board automatically moves backward until it hits the back limit switch. When the back limit switch closes, the rotation motor rotates clockwise four times to fasten the chuck. Finally, the two clamps loosen. The automatic retraction process is accomplished within 25 ± 1 s. The process time can be adjusted by adjusting the motors' speeds. To accomplish the loosening and fastening actions, the back clamp can move in the axial direction but cannot move forward or backward. The balloon catheter driving module applies the *friction-wheel driving method*. During the CVI, the balloon catheter is in the middle of two friction wheels. With the wheels' rotation driven by the motor, the friction advances the balloon catheter along the guidewire. The angiographic injector driving module aims to assist angiography. During the CVI, surgeons need to pay attention to the guidewire/catheter's location in the vessels, which requires injecting a contrast agent occasionally. The guidewire/catheter support module aims to avoid bending of the guidewire and catheter. The guidewire support uses telescopic tubes and the balloon catheter support uses the

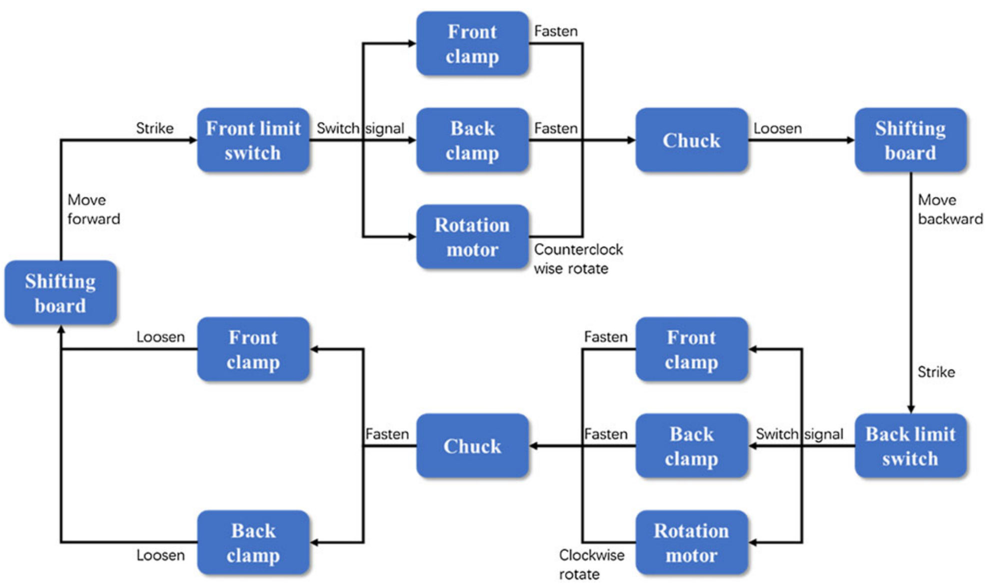

FIGURE 3 Flow chart of the progressive procedure

medical instruments. To solve the problem of cleaning and disinfection, the telescopic tubes, storage coil, chuck, injector and interventional instruments can be easily replaced.

The main console platform is just like the brain and eye of the robotic system. It includes the MMN, PC controller and display centre. Omega 3 (Force Dimension) is selected as the MMN. The PC controller is like the brain of the robotic system, which is in charge of sending instructions, collecting information and processing. The display centre is like the eye of the robotic system, which shows the real-time fluoroscopic image of the tracking position of the guidewire/catheter in vessels. The fluoroscopic image mainly relies on a commercial product – a Siemens C-arm. The platform provides an interface for different MRI images, including human MRI images. In addition, an iPad mini 2 is selected to monitor the surgical site. A camera captures the view of the distal end and transmits it to the Internet, while the iPad with the same login can show the view in real time. During the robot-assisted CVI, surgeons operate the Omega 3 to control the SMN, simultaneously giving instructions and monitoring the position of the guidewire in the vessels. The robotic system does not allow simultaneous movement of the guidewire and balloon catheter, which aims to avoid interference. The PC controller and Omega 3 determine the movement. Omega 3 controls the function of three-axial movements, three-axial force feedback and a customized function key. The three-axial force feedback function aims to give force feelings to surgeons' hands. The *Z*-axis movement is used to remotely control the axial translation of the guidewire driving module. *Y*-axis movement determines the direction of rotation. In balloon catheter driving mode, the *Z*-axis movement is used to remotely control the axial translation of the balloon catheter. In angiographic injector driving mode, the input values determine the injection speeds and volumes. Based on the C-Arm and Omega 3, surgeons can combine the real-time fluoroscopic image with force feedback to accurately perform the CVI.

2.2 | Master–slave control strategy

The robotic system mainly focuses on the guidewire's advancement. A master–slave control strategy was introduced to accomplish this function. The strategy established a master–slave speed control model. Figure 4 shows the establishment of the master–slave coordinates. These coordinates describe the movement of the chuck tip that clamps the flexible guidewire. The origin O_1 of master coordinate O_1 is (0.00, 0.00, 0.00) given by Omega 3's coordinate with gravity compensation. The axial directions of the coordinate O_1 are the axial directions of the Omega 3's coordinate. The origin M of coordinate M is the position of the centre of Omega 3's operation ball. Because Omega 3 does not have rotational DoFs, the axial directions of the coordinate M are the same as those of the coordinate O_1. Therefore, the position of M can be compactly written as a (3 × 1) vector:

$$P_M = \begin{bmatrix} P_x \\ P_y \\ P_z \end{bmatrix}$$

with respect to the coordinate O_1.

The origin O_2 of slave coordinate O_2 is the chuck tip's position when the shifting board hits the back limit switch. This is the movement origin of the SMN. The origin S of coordinate S is the real-time position of the chuck tip and the *Z*-axis direction of coordinate S is the same as that of the coordinate O_2. The *X*- and *Y*-axis directions are the real-time directions according to the chuck tip's rotation angles. Therefore, the position and orientation of point S are written as two (3 × 1) vectors:

$$P_s = \begin{bmatrix} P_x{'} \\ P_y{'} \\ P_z{'} \end{bmatrix}, \quad R_s = \begin{bmatrix} R_x{'} \\ R_y{'} \\ R_z{'} \end{bmatrix}$$

with respect to the coordinate O_2, where

$$P_x{'}, P_y{'}, R_x{'}, R_y{'} \equiv 0.$$

We use the Omega 3's movements to instruct the SMN's movements, and the position of M determines the instruction speeds *V* (V_x, V_y, V_z). We use P_y, P_z to give the instruction speeds V_y, V_z and $V_x \equiv 0$. The positive and negative extreme positions ($\pm P_{ymax}$, $\pm P_{zmax}$) of P_y and P_z output the limit instruction speeds ($\pm V_{ymax}$, $\pm V_{zmax}$) of V_y and V_z. The mathematical relationship between P_m and *V* is

$$V_k = f(P_k) = \frac{P_k}{|P_k|}\left(Q_{i+1}\ln\left(|P_k| - i\frac{P_{k\max}}{n} + 1\right) + V_i\right),$$
$$\left(i\frac{P_{k\max}}{n} \le |P_k| \le (i+1)\frac{P_{k\max}}{n}\right),$$

$$V_i = \ln\left(\frac{P_{k\max}}{n} + 1\right)\sum_{m=0}^{i} Q_m, \quad (k = y, z;\ i = 0, 1, 2, \ldots, n;\ Q_0 = 0),$$

where Q_i is the proportion parameter, and it depends on V_k. Q_i determines the rate of change of the speeds. To increase the response of the small speeds and decrease the response of the large speeds, Q_i decreases when V_k increases. Because the surgeon inserts the guidewire into branches with a large acceleration at a low speed, the Q_i values are large at low speed. Moreover, to reduce the surgical risk, the Q_i values are small at high speed. In order to satisfy the different

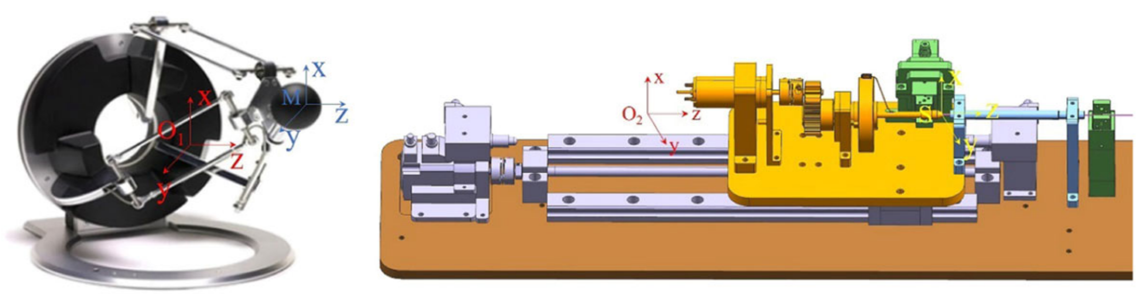

FIGURE 4 Establishment of master–slave coordinates

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requirements of different periods of the CVI, the speed control model was divided into several levels. The control strategy also takes trembling of hands and surgical safety into consideration. In this way, the gradient of the velocity decreases progressively. Figure 5 shows the curve of the equation when $P_k \geq 0$.

The position and orientation of point S change in real time due to the instruction speeds V. The mathematical relationship between P_s, R_s and V is

$$\left[P_z{}' \quad R_z{}'\right] = t \cdot {}_{v}^{pr}T \sum_{i} = 0^n \begin{bmatrix} V_{zi} & \omega \\ \upsilon & V_{yi} \end{bmatrix} + \left[P_{z0}{}' \quad R_{z0}{}'\right],$$

where ${}_{v}^{pr}\boldsymbol{T}_{v}^{pr}T$ is a 2 × 2 relation matrix between the speed and position, t is the time interval of the control strategy and υ, ω are the adjusting phases. In different periods of the CVI, the maximum translational and rotational speeds of the SMN can be changed by the surgeon according to different speed requirements. Thus, υ, ω will be changed accordingly.

To avoid the influence of trembling hands, an 'eccentricity spring' control model was proposed. Because the maximum rotational speed is small, the model mainly focused on the variation in translational

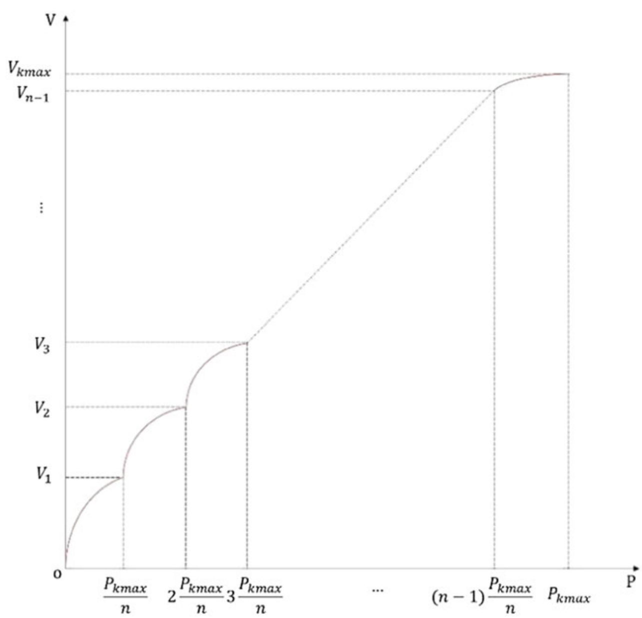

FIGURE 5 Relationship between P_m and V

speed Δ in a very short time (100 ms). Figure 6 shows a conceptual graph of the 'eccentricity spring' control model.

$$\Delta = V_k - V_{k-1}, \quad V_k{}' = V_{k-1} + k \cdot \Delta.$$

$V_k{}'$ is used to instruct the SMN, and V_k and V_{k-1} are obtained from the equation $V_k = f(P_k)$. Five kinds of situation were taken into consideration for different sizes of Δ. In addition, in consideration of the safety of CVI, pulls and pushes were discussed separately. An 'eccentricity spring' model was used to describe the different kinds of situation. The parameter k_1 represents the force imposed on the right side, and k_2 represents the force imposed on the left side. If Δ = 0, the spring is normal. If $0 \leq |\Delta| \leq D_1$**0 < |Δ| ≤ D1**, $k_1 = k_2 = 0$, and the spring is normal. If $D_1 < |\Delta| \leq D_2$**D1 < |Δ| ≤ D2**, $k_1 = k_2 = 1$, and both sides of the spring are in tension. If $D_2 < \Delta$, $k_1 = 0$, $k_2 = 1$, and the left side of the spring is in tension with the right side normal. Thus, the spring centre deviates to the left. If $-D_2 > \Delta$, $k_1 = p_1 > 1$, $k_2 = p_2 > 1$, $p_1 > p_2$, and both sides of the spring are in tension. Thus, the spring centre deviates to the right. If $V_k{}' = V_{k-1} + p \cdot \Delta$, the instruction speed will be $V_k{}'$ until $V_{k+i} \leq V_k{}'$. The threshold D_1 aims to minimize the influence of trembling hands, and the threshold D_2 aims to reduce the error and ensure increased safety of the operation. The control strategy reserved an interface for the force feedback. If the force feedback function is mature in the further study, cooperation between the force feedback and the control strategy can potentially contribute further to the CVI safety.

2.3 | Animal experiment

The robotic system was used to insert a guidewire from a pig's femoral artery to its carotid artery and to inject contrast agent. We also designed a control group, in which the surgeons performed manual animal surgery. The protocol was approved by the Institutional Animal Care and Use Committee (Approval Number: S-20171016-01). A Ba-Ma Mini-pig (weight: 25 kg, body length: 81 cm) was studied. For the image guide, the pig's MRI vascular image was obtained and the vascular part was extracted (Figure 7). The frequently used interventional instruments were inserted in the first *in vivo* trial. The *in vivo* trial was divided into 6 steps: preoperative path planning, surgical path establishment, manual insertion of guiding catheter and guidewire, robot-assisted insertion of guidewire, vascular angiography and postoperative observation.

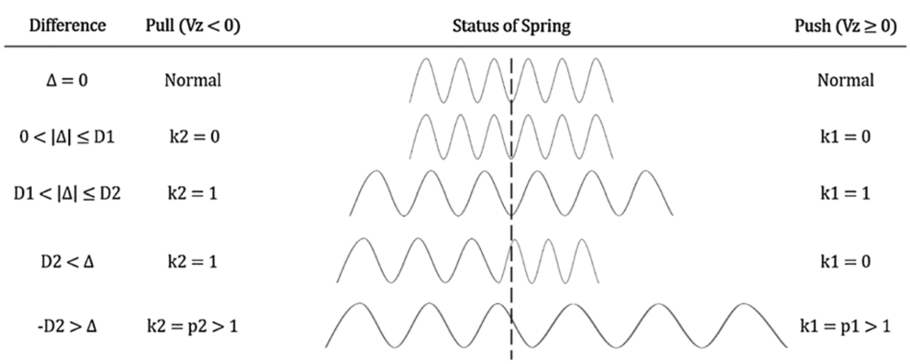

FIGURE 6 Conceptual graph of the 'eccentricity spring' control model

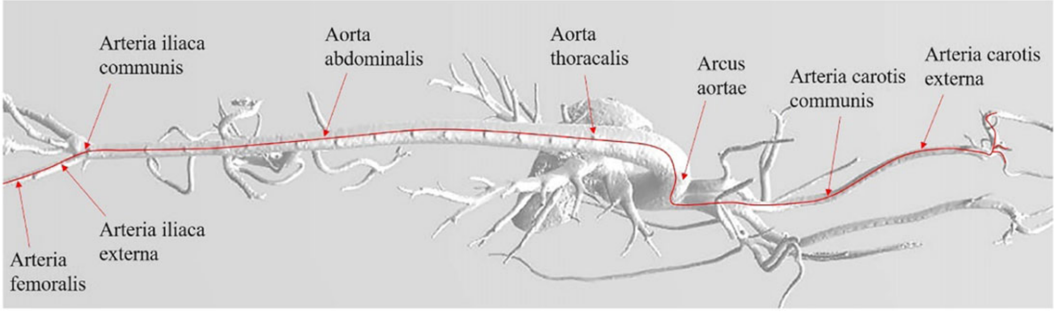

FIGURE 7 Preoperative path planning in the MRI image

2.4 | Preoperative path planning

The surgical approach was expected to be from the pig's femoral artery to the carotid artery. Figure 7 shows preoperative path planning in the MRI image. The intervention path was from arteria femoralis and passed through arteria iliaca externa, arteria communis, aorta abdominalis, aorta thoracalis, arcus aortae, arteria carotis communis, and finally to the secondary vascular network of the arteria carotis externa. The CVI started with a Seldinger puncture at the femoral artery.[24] The guiding catheter and guidewire were manually inserted from the femoral artery to the carotid artery, and then the guidewire was inserted into the secondary vascular network of the carotid artery using the robotic system. After manually withdrawing the guidewire, robot-assisted remote angiography was conducted to observe the shape of the vascular network.

2.5 | Surgical path establishment

The CVI started to establish a vascular pathway, and the Seldinger puncture method was used. The operation was manually performed by a doctor. The surgeon first cut through the skin and muscles at the entrance of the femoral artery and found the femoral artery. Then, the surgeon inserted a puncture needle into the artery. Finally, a sheath was inserted along the puncture needle to establish the vascular pathway.

2.6 | Insertion of guiding catheter

The surgeon manually inserted a portion of the guidewire along the sheath, and then inserted a portion of the guiding catheter along the guidewire. Under X-ray image guidance, the guidewire and the guiding catheter were inserted alternately. The guiding catheter and guidewire were inserted through arteria iliaca externa, arteria iliaca communis, aorta abdominalis, aorta thoracalis, arcus aortae and arteria carotis communis. Finally, the guiding catheter was placed near the arteria carotis externa. Then the surgeon withdrew the guidewire. The guiding catheter was linked to a T-junction and the outer part was supported by a rubber tube.

2.7 | Robot-assisted insertion of guidewire

The surgeon placed the guidewire in the storage coil of the SMN and walked out of the operating room. In front of the MMN, the surgeon operated Omega 3 to remotely control the SMN for advancement and rotation of the guidewire under X-ray image guidance. When the guidewire passed the vascular branches, the surgeon operated the *Y*-axis and *Z*-axis movements of Omega 3, and thus the SMN simultaneously advanced and rotated the guidewire to pass the branches. Eventually, the guidewire was inserted into the secondary vascular of the arteria carotis externa. In the control group, the surgeons manually inserted the guidewire into the same secondary vascular of the arteria carotis externa through the same intervention path.

2.8 | Vascular angiography

After the robot-assisted procedure to insert the guidewire, the surgeon withdrew the guidewire. Remote angiography was performed using the angiographic injector driving module of the SMN. The surgeon input the values of the injection speed and volume to instruct the driving module to complete the injection of contrast agent. At the same time, real-time fluoroscopy recorded the vascular image and showed the vascular shape. In this trial, 5 ml of the contrast agent was used, and the injection speeds were 1 ml/s and 2 ml/s. The surgeon repeated the angiography 6 times.

2.9 | Postoperative observation

After completing the angiography, the catheter and sheath were withdrawn. The femoral artery was sutured. After the operation, the animal was kept under observation.

3 | RESULTS

The robotic system successfully accomplished the intended purpose of inserting a guidewire from a pig's femoral artery to its carotid artery and injecting a contrast agent. The intervention path followed the predetermined route, as shown in Figure 7. The guidewire was successfully inserted into the secondary vascular of the arteria carotis externa. After the trial, the vital signs of the pig were stable, and its activity was free after the anaesthesia. Under observation for several days, the pig was still alive and the vital signs were good. All robot-assisted procedures (Figure 8) were accomplished with the robotic system without any vascular rupture. The time taken in the robot-assisted procedure and in the control group is shown in Table 1. The time for the whole procedure is just the summation of the times for vascular puncture, insertion of the guiding catheter, insertion of the guidewire and angiography. The insertion of the guidewire at key position means

FIGURE 8 Robot-assisted CVI procedures. A, Manual insertion of the guiding catheter. B, Robot-assisted insertion of the guidewire

TABLE 1 The procedure time of the animal experiment

	Experimental group (min)		Control group (min)	
Procedure	**Surgery**	**Fluoroscopy**	**Surgery**	**Fluoroscopy**
Whole procedure	83	22	58	11
Vascular puncture	33	0	33	0
Insertion of guiding catheter	13	5	13	5
Insertion of guidewire	27	14	4	3
Insertion of guidewire at key position	6	5	2	2
Angiography	10	3	8	3

that we inserted the guidewire into the secondary vascular of the arteria carotis externa. The time for fluoroscopy recorded the duration of the period of X-ray image guidance, which might be longer than the actual time for fluoroscopy. The surgical time of the control group included the time moving to and from the operating room.

Based on our remote-controlled master–slave design, the surgeon operated the Omega 3 at a safe distance with X-ray image guidance and successfully advanced the guidewire into the target vascular without visible delay. The maximum propulsion speed of the guidewire inside the catheter was approximately 40 cm per minute. The guidewire was successfully inserted into four secondary branches of the pig's carotid artery (Figure 9(A)). Finally, angiography was done six times using different injection speeds. Figure 9(B) shows the images before and after angiography. The injection speed of the angiography in the first three trials is half of that in the second three trials. The intended robot-assisted procedures to insert the guidewire were successfully conducted without the surgeons being exposed to X-rays.

4 | DISCUSSION

4.1 | Robotic system design

Compared with the existing robotic system, our robotic system combined the advantages of the *progressive driving method* and *continuous driving method* to accomplish advancement and rotation of the guidewire. The travel with a step of 200 ± 0.5 mm solves the problem

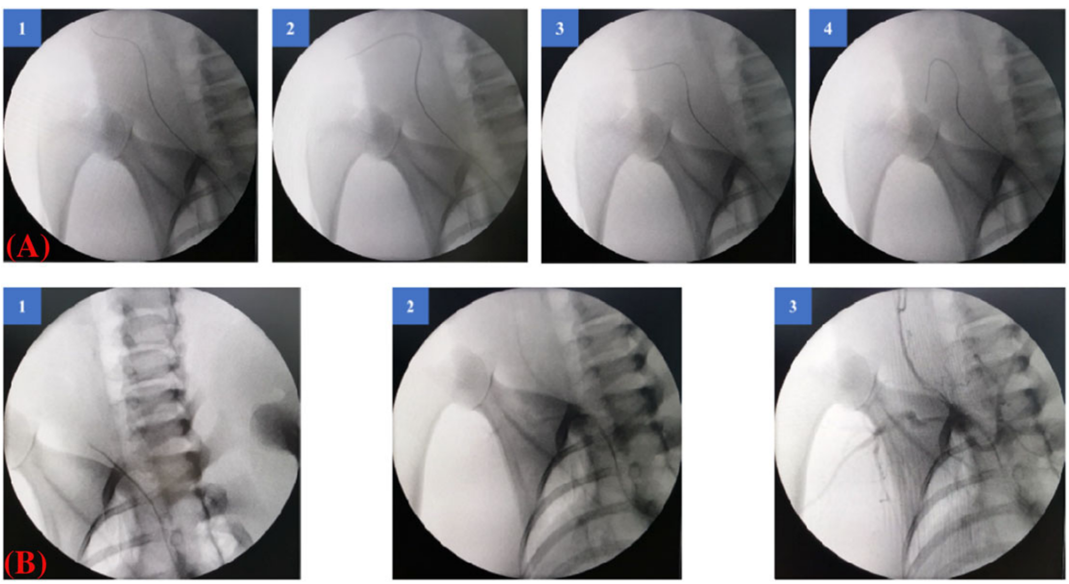

FIGURE 9 Fluoroscopic images of guidewire and angiography. A, Fluoroscopic images of the guidewire inserted into four secondary branches of the carotid. B, Fluoroscopic images before and after the repeated angiography

of little operating space in the *progressive driving method* and the issue of heavy weight of the *continuous driving method*. The *progressive driving method* solves the flexibility and length limitation of the *continuous driving method*. The balloon catheter driving module used the *friction-wheel driving method*. The balloon catheter was inserted along the guidewire, so one DoF and the control accuracy were enough to drive the balloon catheter. The module avoided the lower control accuracy and took advantage of the small operation space. Moreover, no existing robotic system has added a remote-controlled angiographic injector, which is a frequently used function. Our angiographic injector driving module decreased the time to and from the operating room.

In the CVI, surgeons usually determine the position of the guidewire in blood vessels via real-time fluoroscopic imaging and force feedback attached to their hands, and in response, surgeons can perform appropriate operations. Hence, the robotic system provides real-time fluoroscopic images and a force feedback function. The added 6-axis force/torque transducer measures the forces and torques of the guidewire tail, which is similar to the conditions of manual operation. Because the validity of the force feedback cannot be ensured and the description and development of the force feedback are not easy, the force feedback is not applied to Omega and is not shown in this trial. A monitor is introduced to avoid accidents in the distal end.

The potential advantages of our CVI robotic system are summarized as follows.

1. It combines the advantages of the three common methods and avoids their disadvantages as far as possible.
2. It uses an available and reliable remote-controlled master–slave robotic system design, which, to a certain extent, prevents the surgeons from exposure to X-ray radiation.
3. A 6-axis force/torque feedback function and real-time fluoroscopic image guidance potentially provide a similar surgical experience for the surgeons and improve the surgical safety.
4. A remote-controlled angiographic injector makes it possible for surgeons to be completely outside the operating room.

4.2 | Animal experiment

The success of the first *in vivo* trial preliminarily indicates the success and feasibility of the design of our CVI robotic system. The master–slave design meets the surgical requirements. The surgeon was satisfied with the usability of the robotic system.

In the first *in vivo* trial, we inserted the guidewire and injected a contrast agent using our robotic system. The insertion of the guiding catheter was completed manually. Manual insertion of a guiding catheter is relatively easy for experienced surgeons and quick to complete. As Table 1 shows, the time taken for the experimental group is longer than that for the control group. The vascular puncture took up most of the time. This is partially related to the surgeons' experience. The surgeons operated on a pig and were not very familiar with its anatomic structure, so they spent a lot of time finding the pig's femoral artery during the vascular puncture procedure. The manual insertion of the guiding catheter into this pig cost more time than the usual insertion of a guiding catheter into a human body. This is mostly because of the inconvenience of the X-ray machine and the fact that the surgeons were not familiar with the adjustment of position and orientation of the C-arm. The time for robot-assisted insertion of the guidewire is much longer than that for manual insertion for several reasons. First, for safety, the maximum translational speed set of the guidewire driving module is far less than the normal manual speed of operation and the retracting speed set of the retraction process is relatively slow. Each retract step took about 30 s, and we had four retract steps during insertion of the guidewire. Second, we had to enter the operating room and adjust the positions and orientations of the C-arm, which aimed to track the guidewire's position and provide real-time fluoroscopic image guidance. Third, the surgeon was not familiar with the operation of the robotic system, and thus his robotic operation was far slower than his manual operation. Finally, the guidewire assembly took a lot of time. Moreover, the time for fluoroscopy of the robot-assisted procedure for insertion of the guidewire is much longer than that for manual operation. The slow robotic operation increased the time for fluoroscopy and we determined the position of the guidewire so many times using fluoroscopy. However, the experimental group time for insertion of the guidewire at the key position and angiography is a little longer than the time for these procedures in the control group, which indicates the efficiency and availability of our newly developed robotic system. We believe that, with more training and trials, the experimental group time and time for fluoroscopy can be shortened. In addition, Wang *et al.*[25] also tested their robot in an adult dog, and they inserted the catheter into the renal artery, left atrium, right atrium, left ventricle and right ventricle. Although their time for robotic surgery was shorter than ours, the diameters of the arteries they inserted into were larger than those in our case. Besides, we inserted the guidewire from the femoral artery to the carotid artery, the interventional path was longer and more complex than theirs. Thus, our *in vivo* trial and robotic system potentially provided more possibilities for the robot-assisted CVI. Additionally, their dog had a shorter body than our tested pig, which increased our time for robotic surgery.

Figure 9(A) shows the different shapes of the fluoroscopic images in the four secondary branches, which indicates the successful accomplishments of the trials on insertion of the guidewire and the feasibility and effectiveness of the guidewire driving module. Figure 9(B2) and Figure 9(B3) show fluoroscopic images of the angiography in first three trials and the second three, respectively. The angiography results in the second three trials are significantly better than those in the first three, and the surgeon was satisfied with the results of the second set. Furthermore, with the injection speeds increasing in a certain range, the angiography results will become better. The results of the angiography trials are consistent with those from clinical surgery. Injections of each of the two kinds of angiography were conducted three times to ensure stability and effectiveness of the angiography results, and the results in one kind of angiography were similar to those in the other kind. Thus, the injection speed used in the second angiography and the 5 ml injection per step can be used, and the design is fully proved effective.

5 | CONCLUSION

In summary, the first *in vivo* trial of the newly developed CVI robotic system was satisfying. The results of this trial indicate that the robot design is suitable for its intended purpose. The positive feedback of the surgeons is encouraging for further development of the device. More trials are planned to measure the forces and torques and to test the robot-assisted insertion of a balloon catheter. After carrying out the force and torque measurements sufficiently and analysing them, the force and torque feedback functions of the robot will be accomplished.

ACKNOWLEDGEMENTS

This work was supported by High Technology Research and Development Program of China (863 Program, No. 2015AA043203), Natural Science Foundation of China (No. 61672341, No.61471349), the project of Science and Technology Commission of Shanghai municipality (No. 17441903800), the project of major program of National Natural Science Foundation of China (No. 61190124, 61190120), Basic Discipline Layout Project of Shenzhen City (No. JCYJ20150731154850923) and Shenzhen Engineering Laboratory for Key Technology on Intervention Diagnosis and Treatment Integration.

CONFLICT OF INTEREST

All the authors declare they have no conflict of interest.

ETHICAL APPROVAL

All applicable international, national and/or institutional guidelines for the care and use of animals were followed. All procedures performed in studies involving animals were in accordance with the ethical standards of the institution at which the studies were conducted.

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How to cite this article: Shen H, Wang C, Xie L, Zhou S, Gu L, Xie H. A novel remote-controlled robotic system for cerebrovascular intervention. *Int J Med Robotics Comput Assist Surg*. 2018;14:e1943. https://doi.org/10.1002/rcs.1943